

BS EN ISO/IEC 80079-34:2011



BSI Standards Publication

Explosive atmospheres

Part 34: Application of quality systems
for equipment manufacture (ISO/IEC
80079-34:2011, modified)

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National foreword

This British Standard is the UK implementation of EN ISO/IEC 80079-34:2011. It supersedes BS EN 13980:2002 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee EXL/23, Explosion and fire precautions in industrial and chemical plant.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Compliance with a British Standard cannot confer immunity from legal obligations.

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Amendments/corrigenda issued since publication

Date	Text affected
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English version

**Explosive atmospheres -
Part 34: Application of quality systems for equipment manufacture
(ISO/IEC 80079-34:2011, modified)**

Atmosphères explosives -
Partie 34: Application des systèmes de
qualité pour la fabrication d'équipements
(ISO/CEI 80079-34:2011, modifiée)

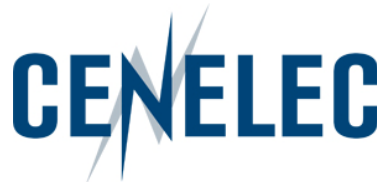
Explosionsgefährdete Bereiche -
Teil 34: Anwendung von
Qualitätsmanagementsystemen für die
Herstellung von Geräten
(ISO/IEC 80079-34:2011, modifiziert)

This European Standard was approved by CEN and CENELEC on 25 May 2011.

CEN and CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN and CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN and CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN and CENELEC members are the national standards bodies and national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.



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Foreword

The text of ISO/IEC 80079-34:2011 has been prepared by Technical Committee IEC TC 31 "Equipment for explosive atmospheres" of the International Electrotechnical Commission (IEC) and has been taken over as EN ISO/IEC 80079-34:2011 by Technical Committee CEN/TC 305 "Potentially explosive atmospheres – Explosion prevention and protection" the secretariat of which is held by DIN. The enquiry took place at ISO/CEN level (31M/31/CDV, CEN Project = WI 00305114). However, the vote on 31M/45/FDIS took place at IEC/CLC level (agreement between ISO and IEC, see also D130/103), under the responsibility of the Technical Committee CENELEC TC 31 "Electrical apparatus for potentially explosive atmospheres".

The text of document 31M/45/FDIS, future edition 1 of ISO/IEC 80079-34:2010, prepared by Technical Committee IEC TC 31 "Equipment for explosive atmospheres", was submitted to the IEC-CENELEC parallel vote.

A draft amendment, prepared by the Technical Committee CEN TC 305 "Electrical Potentially explosive atmospheres – Explosion prevention and protection", was submitted to the CENELEC formal vote.

The combined texts were approved by CEN and CENELEC as EN ISO/IEC 80079-34 on 2011-05-25.

This document supersedes EN 13980:2002.

The significant changes with respect to EN 13980:2002 are the following:

- references have been changed, especially references to CEN/CENELEC and their publications have been changed to references to international available publications;
- foreword and scope have been adapted to international requirements;
- terminology has been changed and adapted to terminology being more customary in the international standardization (e. g. "notified body" has been modified to "body responsible for verification");
- information relevant to particular types of protection has been amended with
 - Ex t - dust ignition protection by enclosure,
 - gas detectors and
 - flame arresters;
- Annex B has been renamed as "Verification criteria for elements with non-measurable paths used as an integral part of a type of protection";
- B.3 has been modified;
- information relevant to equipment and protective systems according to standards harmonized under Directive 94/9/EC are given in new Annex ZB.

This standard should be read in conjunction with EN ISO 9001:2008.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN and CENELEC shall not be held responsible for identifying any or all such patent rights.

The following dates were fixed:

- latest date by which the EN has to be implemented at national level by publication of an harmonized national standard or by endorsement (dop) 2012-05-25
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2014-05-25

Annex ZB provides information on those aspects that the quality system should address with respect to particular protection laid down in harmonized standards under Directive 94/9/EC, e.g. types of protection for non-electrical equipment or components, equipment according to specific product standards and autonomous protective systems. It does not add to or otherwise change the requirements of this standard.

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive 94/9/EC. See Annex ZZ.

The State of the Art is included in Annex ZY “*Significant changes between this European Standard and EN 13980:2002*”.

Annexes ZA, ZB, ZY and ZZ have been added by CEN and CENELEC.

Annex ZA (normative)

Normative references to international publications and the corresponding European publications

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60050-426	-	International Electrotechnical Vocabulary - Part 426: Equipment for explosive atmospheres	-	-
IEC 60079-0	-	Explosive atmospheres - Part 0: Equipment - General requirements	EN 60079-0	-
ISO/IEC 17050-1	-	Conformity assessment - Supplier's declaration of conformity - Part 1: General requirements	EN ISO/IEC 17050-1	-
ISO 9000	2005	Quality management systems - Fundamentals and vocabulary	EN ISO 9000	2005
ISO 9001	2008	Quality management systems - Requirements	EN ISO 9001	2008

Annex ZB (informative)

Information relevant to equipment and protective systems according to standards harmonized under Directive 94/9/EC

ZB.1 Introduction

This annex provides information on those aspects that the quality system should address with respect to particular protection laid down in harmonized standards under Directive 94/9/EC, e.g. types of protection for non-electrical equipment or components, equipment according to specific product standards and autonomous protective systems. It does not add to or otherwise change the requirements of this standard.

This annex provides information how to meet the requirements of this standard, recognizing that other methods achieving the same objectives are equally acceptable; it also draws attention to aspects of requirements that may not be readily apparent to those unfamiliar with quality systems for products intended for use in potentially explosive atmospheres.

The examples can be used by manufacturers to check whether the safety-relevant aspects are considered in the quality system and covered by adequate procedures (see 7.1). They can also be used for internal or external quality audits (see 8.2).

NOTE The following examples do not cover all protection concepts but give some advice and will be supplemented to in the next edition.

ZB.2 Non-electrical equipment (EN 13463-1)

ZB.2.1 General

The following safety aspects as specified in the technical file should be realised by systematic production techniques and/or verifications and tests on the basis of written procedures.

For dust ignition, protection the safety aspects laid down in A.10 may also apply.

ZB.2.2 Non-metallic parts

- Material characteristics;
- finish;
- surface resistance;
- surface area of non-conductive parts;
- limitation of thickness;
- measures for charge bonding (earthed frames).

ZB.2.3 Casing and external parts

- Material of the casing and content of light metals;
- protection of removable parts against unintentional or inadvertent removal;
- materials used for cementing.

ZB.2.4 Earthing and equipotential bonding of conductive parts

- Earthing terminal;
- effective connection of conductive parts;
- voltage equalising cables.

ZB.2.5 Light transmitting parts

- Material;
- integrity;
- guards and protective covers.

ZB.2.6 Ingress protection (IP)

- Weld continuity;
- fitting of gaskets and seals;
- continuity of moulded grooves and tongues;
- application of cements.

ZB.2.7 Completed products

- Instructions are delivered with the equipment;
- instructions include information regarding embedded equipment and components;
- intended marking is fixed;
- intended warning labels are fixed;
- after final testing, products are protected against foreseeable injuries during storage and transport.

ZB.3 Protection by flow restricting enclosure „fr“ (EN 13463-2)

Safety aspects are covered by the general clause for non-electrical equipment (EN 13463-1).

ZB.4 Protection by flameproof enclosure „d“ (EN 13463-3)

The same safety aspects as for electrical equipment apply (see A.3; for aspects of dust ignition protection, see also A.10).

ZB.5 Protection by constructional safety „c“ (EN 13463-5)

ZB.5.1 General

In addition to the safety aspects for non-electrical equipment in ZB.2, the following safety aspects are relevant.

ZB.5.2 Metal-based material

- Material name complying with the requirement;
- material properties (composition with regard to corrosion, thermal conduction and mechanical sparks, mass fraction of aluminium, titanium, magnesium, zirconium, flammability);
- cracks, inclusions, blow holes and porosity (either by a visual test or by another suitable test method depending on exposure);
- heat treatment (e.g. hardening, tempering);
- dimensional accuracy including all parts without machining.

ZB.5.3 Machining

- Compliance with tolerances for shape, position, concentricity, quality of finish;
- dimensional accuracy of functional surfaces (e.g. tolerances for diameters, especially for indicator units preadjustment and correct polarity);
- depth and configuration of cut-in to ensure the constructionally intended stress concentration.

ZB.5.4 Cemented joints and potted assemblies

- Shelf-life and storage of adhesives and casting compounds;
- mixing procedure;
- surface treatment (degreasing or equivalent measures are usually required immediately before the potting-process to ensure proper adhesion);
- curing process, which should include curing time, any relevant environmental factors and all provisions made to ensure that the curing process will proceed without disturbance.

ZB.5.5 Assembling

- Correct components and parts;
- distances between moving parts or between fixed and moving parts;
- equipotential bonding between subassemblies;
- mechanical seals;
- protective covers.

ZB.5.6 Routine tests

- Sealing systems (fit, lubrication, initial tension, primary pressure);
- dynamic vibrations (e.g. critical rotation speed, bearing at standstill or at transport);
- functional test of the complete assembly (distance between rotor/stator modules, clamping, clearance, free room of motion).

ZB.5.7 Power transmission systems

- Conditions of the lubrication;
- belt tension;
- equipotential bonding (especially couplings, belt drives, chain drives, gears, shafts);

ZB.6 Protection by control of ignition sources „b“ (EN 13463-6)

ZB.6.1 General

In addition to the safety aspects for non-electrical equipment (see ZB.2), the following safety aspects are relevant.

ZB.6.2 Ignition protection system

- Selection of appropriate sensors, actuators and other relevant parts (e.g. temperature range);
- indicating devices marked to indicate the maximum and minimum operating levels;
- specification of tests and all other necessary information in the instructions.

ZB.6.3 Installation

- Installation of sensors and actuators (fail safe characteristics, separate power supply);
- connection installation of sensors (e.g. offset);
- position of sensors;
- correct interfacing;
- avoidance of delay elements;
- avoidance of unintended modification of set values;
- independent power supply.

ZB.6.4 Tests

Typically, the following tests and verifications should be done at the manufacturer's site.

- tests before initial operation or specification of these tests in the instructions;
- functioning;

- accuracy;
- response behaviour;
- fail-safe;
- interlocking of settings;
- specification of tests in the course of maintenance in the instructions.

If the ignition protection system is assembled during installation at the user's site, the instruction should give specific guidance how to carry out these tests.

ZB.7 Protection by pressurised enclosures „p“ (EN 13463-7)

The same safety aspects as for electrical equipment apply (A.6).

ZB.8 Protection by liquid immersion „k“ (EN 13463-8)

ZB.8.1 General

In addition to the safety aspects for non-electrical equipment (see ZB.2), the following safety aspects are relevant.

ZB.8.2 Protective liquid

- Type of the liquid;
- liquid level or flow rate or pressure (depending on the system).

ZB.8.3 Casing

- Leak tightness of the protective liquid closed loop;
- protections against unintentional or inadvertent of fastenings;
- measures against protective liquid impurity.

ZB.8.4 Measuring or indicating devices

- Dipstick;
- marking of maximum/minimum criteria for the protective liquid level;
- marking of maximum permissible angle of inclination.

ZB.9 Fans (EN 14986)

ZB.9.1 General

The following safety aspects as specified in the technical file should be realised by systematic production techniques and/or verifications and tests on the basis of written procedures.

ZB.9.2 Material

- Selection of specified materials; material name complies with the requirement;
- material properties (composition with regard to corrosion, thermal conduction and mechanical sparks, mass fraction of aluminium, titanium, magnesium, zirconium, flammability);
- cracks, inclusions, blow holes and porosity (either by a visual test or another suitable test method depending on exposure);
- heat treatment (e.g. hardening, tempering);
- dimensional accuracy including all parts without machining.

ZB.9.3 Assembled equipment and protective systems

- Adaption of suitable electrical equipment (explosion group, temperature class, equipment category);
- adaption of specified protective systems for fans of category 1G.

ZB.9.4 Routine tests

- Sealing systems (fit, lubrication, initial tension, primary pressure);
- dynamic vibrations (e.g. critical rotation speed, bearing at standstill or at transport);
- functional test of the complete assembly (distance between rotor/stator modules, clamping, clearance, free room of motion);
- excess rotation speed;
- thickness of linings;
- impeller-shaft attachment (avoidance of drift, joint is secured against loosening);
- mounting of autonomous protective systems, if applicable;
- functional test of the temperature monitoring devices in the flame arresters, if applicable;
- pressure test for fans of category 1G, if applicable.

ZB.10 Petrol dispensers (EN 13617-1)

ZB.10.1 General

The following safety aspects as specified in the technical file should be realised by systematic production techniques and/or verifications and tests on the basis of written procedures.

ZB.10.2 Electrical installation

- Type of cable;
- installation of cable;
- correct wiring;

- connection technique;
- torque of screwed connections (traceability).

ZB.10.3 Information for safe operation

- Availability of operating instructions;
- marking on the type label (technical data, type of protection, etc.);
- passing on of warning notes;
- maintenance instructions.

ZB.10.4 Assembly groups

- Drives or electrical equipment;
- subassemblies (gears, couplings, belts);
- components;
- safety-relevant verifications for the interconnection of apparatus, subassemblies and components;
- protective systems within the gas recirculation system.

ZB.10.5 Assembling

- Correct components and parts;
- minimum distances of moving parts (rotor/stator);
- measures performed for equipotential bonding (to ground, between subassemblies);
- protective covers.

ZB.10.6 Monitoring equipment

- Installation of sensors and actuators (fail safe characteristics, separate power supply);
- installation of sensors (position, correct interfacing, prevention of lag elements);
- tests during maintenance (according to operating instructions);
- functional tests and precision control;
- insulation of cables.

For additional information, see also ZB.6.

ZB.10.7 Electrostatic discharge capacity

- Materials (electrostatic discharge capacity resp. surface resistance of non-metallic parts, belts, tubes, etc.);
- limitation of the surface area for the corresponding explosion group;
- thickness of the material for the corresponding explosion group.

ZB.10.8 Routine tests

- Pressure test;
- deactivation/activation of the controlling system before release;
- insulation resistance;
- functional test.

ZB.11 Electrostatic spraying equipment (EN 50050)

ZB.11.1 General

The following safety aspects as specified in the technical file should be realised by systematic production techniques and/or verifications and tests on the basis of written procedures.

ZB.11.2 Electrical assembly

The characteristics of the following parts including control devices and accessories should be tested with respect to the application in electrostatic spraying equipment; this means normally that the marking on the component parts or the packaging is verified where appropriate statistical methods may be applied as necessary:

- selection of the high voltage transformer (type, manufacturer, insulation, voltage);
- equipotential bonding and grounding system for the spraying equipment and control device;
- number of stages of the cascade and turn ratio of the high-voltage transformer and the capacity of the cascade;
- assembling, type and value of each current limiting resistor, diode, Zener diode, capacitor or any other safety-relevant component (e.g. hardware-watch-dog);
- manual or automatic assembly of printed circuit boards;
- fixing and soldering of transformer, diodes, capacitors of the cascades;
- date of expiry and storage of adhesives and casting compounds;
- mixing procedures (e.g. pressure, temperature, time characteristics);
- surface treatment (degreasing or equivalent measures are usually required immediately before the potting process to ensure proper adhesion);
- processing, e.g. filling instructions, void-free potting, temperature conditions;

- curing process including: curing time, all relevant environmental factors, provisions made to ensure that the curing process will proceed (e.g. mains power failure detection);

NOTE 1 For printed circuit boards, the manufacturer should provide a list of safety-relevant electronic components (e.g. resistors, Zener diodes) used. 100 % of the listed components should be tested. This can be done by visual test or for SMD-components by assuring correct charging of the component insertion automat and by visual test of correct positioning or by automated test equipment (ATE) provided that each individual safety-relevant electronic component is considered and that a visual inspection is performed to check the type code and direction of components.

NOTE 2 If the SMD-insertion automat selects the correct component carrier on the basis of a value measurement of the component, this measuring function should be calibrated.

- selection of cable (high voltage, low voltage);
- length, type and electric strength of the cable including grounding and screening if applicable;
- connection technique and fixing method of cables between controlling device and spraying equipment.

ZB.11.3 Mechanical assembly

- Materials of spraying equipment and control devices should be inspected for cracks, inclusions, bubbling and porosity;
- dimensional accuracy, evenness, surface roughness, fitting accuracy, depth of bushings, flanges and threads of the nozzles of spraying equipment and accessories (extensions, angles, etc.);
- torque of the screwed connections if safety relevant;
- IP protection (see ZB.2.6 for details);
- continuous weld seams;
- mounting of annular and flat gaskets;
- continuity of moulded tongues and grooves;
- application of adhesives.

ZB.11.4 Tests

- I_{\max} of the spraying equipment with associated accessories;
- U_{\max} of the spraying equipment with associated accessories;
- open-circuit monitoring between spraying equipment and control device, if applicable;
- response of the safety facilities in case of simulated malfunction, if applicable.

Where spraying equipment and associated accessories are intended to be combined user-defined, criteria of acceptance for the tests should consider the worst case.

ZB.12 Protective systems

ZB.12.1 General

The following safety aspects as specified in the technical file should be realised by systematic production techniques and/or verifications and tests on the basis of written procedures:

- the properties of dissipative plastics are proven by the manufacturer by dint of a material certification and examined at least through routine tests (e.g. in accordance with HD 429, neglecting the climate);
- layer thicknesses of non-conductive coatings are examined by routine tests at a sufficient amount of adequate measuring points;
- packing boxes without a temperature control are tightened with a predefined torque;
- every examination is documented.

NOTE Routine tests can be a requirement in certificates or be required by the auditing notified body.

ZB.12.2 Explosion resistant equipment (EN 14460)

The following safety aspects as specified in the technical file should be realised by systematic production techniques and/or verifications and tests on the basis of written procedures:

- pressure shock resistant devices are manufactured according to EN 13445-4, if designed according to EN 13445-3;
- pressure test for each cast part is carried out;
- pressure test is carried out according to EN 14460:2006, Table 1, lasting at least 3 min (routine test); if this is impossible due to technical or safety-relevant reasons, there must be material;
- certificates according to EN 10204, or non-destructive tests of the weld seams (at least supersonic) as well as a dimensions comparison must be carried through;
- weld seams are tested considering the weld seam factor;
- material certificates according to EN 13445-2 are available for the pressure-loaded main parts;
- correct marking and warning labels (e.g. maximum operational pressure, maximum operational temperature, if necessary);
- correct assembling.

For further aspects regarding pressure resistance, see A.3.

ZB.12.3 Explosion venting devices (EN 14797)

The following safety aspects as specified in the technical file should be realised by systematic production techniques and/or verifications and tests on the basis of written procedures:

- the static response pressure of explosion venting devices is determined (in the case of reusable explosion venting devices, e.g. explosion venting valves, this should be realised in a routine test; in the case of non-reusable explosion venting devices, e.g. bursting discs, it could be realised through random sampling);
- leak test, if applicable;

- material certificates for the explosion venting devices (e.g. for the plates processed, rubber clamp profiles);
- stability tests are required for explosion venting valves as well as for the baskets for flameless devices;
- dimensional accuracy (e.g. gaps, predetermined breaking points of the bursting discs, wall thicknesses of the processed plates;
- gaskets;
- mass of the insulation, if applicable;
- heating installations on the moveable elements, if applicable;
- weld seams are tested considering the weld seam factor;
- correct marking and warning labels (e.g. maximum operational pressure, maximum operational temperature, if necessary);
- correct assembling.

ZB.12.4 Explosion isolation systems (EN 15089)

The following safety aspects as specified in the technical file should be realised by systematic production techniques and/or verifications and tests on the basis of written procedures:

- sensor-actor-chain's closing speed are tested in routine tests (e.g. of squeeze valve, slide valve, butterfly valve, active Ex valve);
- operating values of all sensors (e.g. pressure, temperature, light);
- dimensional accuracy, particularly of the sealing elements;
- dimensions of enclosure, rotors, blades, discs and gaskets;
- gaps between rotors and enclosures of rotary valves;
- stability of isolation systems for high pressures are tested in compliance with EN 14460;
- closing force of passive explosion protection valves;
- installations in the interior necessary for safe operation (e.g. rotors of rotary valves, blades, discs, sleeves);
- proof of material;
- welding procedure, if applicable;
- correct marking and warning labels (e.g. maximum operational pressure, maximum operational temperature, if necessary);
- correct assembling.

Annex ZY
(informative)

Significant changes between this European Standard and EN 13980:2002

This European Standard supersedes EN 13980:2002.

Table ZY.1 — Significant changes between this European Standard and EN 13980:2002

Significant changes	Clause	Type		
		Minor and editorial changes	Extension	Major technical changes
Reference to ISO 9001:2008	Scope and all	X		
New reference to ISO and IEC standard	2	X		
Adding of new definition	3	X		
Change of certain term as: <ul style="list-style-type: none"> • EC type examination certificate by Ex certificate • Notified Body by Certification Body • Equipment documents by Technical documentation 	All	X		
Adding of a note to explain that the body responsible for the quality assessment may be different from the body who issued the Ex certificate	4.2.3 g)	X		
Adding of new clause specifying that the manufacturer shall have a documented process to annually check the validity of all document relating to Ex products	4.2.3 h)	X		
The note regarding the fact the manufacturer has to retain adequate quality records to demonstrate conformity of the product is now a requirement already required by the ATEX directive.	4.2.4	X		
The responsibilities and authority of the person who reviews the Ex certificate and the technical documentation and who identifies any changes that affect product compliance with the certificate need to be defined.	5.5.1 g)	X		
All people having an impact on Ex compliance need to receive appropriate training.	6.2.2	X		
The Authorised person has to approve any changes that could compromise Ex compliance.	7.3.7	X		

Table ZY.1 (continued)

Significant changes	Clause	Type		
		Minor and editorial changes	Extension	Major technical changes
Move from 5.4.2 the fact that the manufacturer has to facilitate the audit of the supplier if required by the Notified Body	7.4.1 f)	X		
Alternative of how to be sure that the suppliers have the current version of the documentation	7.4.2 d)		X	
Explanation of what is required for material purchasing	7.4.3 j)	X		
Move from 8.2.3 of the requirement regarding that special validation need to performed to validate of the processes for production	7.5.2	X		
Update of the example of what need to be checked for each type of protection	Annex A	X		
Addition of example for type of protection 't', gas detectors and flame arrestors				

NOTE 1 The technical changes referred to include the significant technical changes from the revised EN but this is not an exhaustive list of all modifications from the previous version.

Explanations

A) Definitions

Minor and editorial changes

clarification
decrease of technical requirements
minor technical change
editorial corrections

Changes in a standard classified as 'Minor and editorial changes' refer to changes regarding the previous standard, which modify requirements in an editorial or a minor technical way. In addition, changes of the wording to clarify technical requirements without any technical change are classified as 'Minor and editorial changes'.

A reduction in level of existing requirement is also classified as 'Minor and editorial changes'.

Extension

addition of technical options

Changes in a standard classified as 'extension' refers to changes regarding the previous standard, which add new or modify existing technical requirements, in a way that new options are given, but without increasing requirements for equipment that was fully compliant with the previous standard. Therefore these 'extensions' will not have to be considered for products in conformity with the preceding edition.

Major technical changes

addition of technical requirements
increase of technical requirements

Changes in a standard classified as 'Major technical change' refer to changes regarding the previous standard that add new technical requirements or increase the level of existing technical requirements, in a way that a product in conformity with the preceding standard will not always be able to fulfil the requirements given in the new standard. 'Major technical changes' have to be considered for products in conformity with the preceding edition. For every change classified as 'Major technical change', additional information is provided in Clause B) of Annex ZY.

NOTE 2 These changes represent current technological knowledge ¹⁾. However, these changes should not normally have an influence on equipment already placed on the market.

B) Information about the background of 'Major technical changes'

None

1) See also ATEX Guidelines (2009), 10.3 and Annex ZZ.

Annex ZZ (informative)

Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex II of the EC Directive 94/9/EC.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive(s) concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

Bibliography

Add the following references:

[ATEX Guidelines \(Third edition – June 2009\)](#)

EN 10204, *Metallic products – Types of inspection documents*

EN 13445-2, *Unfired pressure vessels – Part 2: Materials*

EN 13445-3, *Unfired pressure vessels – Part 3: Design*

EN 13445-4, *Unfired pressure vessels – Part 4: Fabrication*

EN 13463-1, *Non-electrical equipment for use in potentially explosive atmospheres – Part 1: Basic method and requirements*

EN 13463-2, *Non-electrical equipment for use in potentially explosive atmospheres – Part 2: Protection by flow restricting enclosure 'fr'*

EN 13463-3, *Non-electrical equipment for use in potentially explosive atmospheres – Part 3: Protection by flameproof enclosure 'd'*

EN 13463-5, *Non-electrical equipment intended for use in potentially explosive atmospheres – Part 5: Protection by constructional safety "c"*

EN 13463-6, *Non-electrical equipment for use in potentially explosive atmospheres – Part 6: Protection by control of ignition source 'b'*

EN 13463-7 ²⁾, *Non-electrical equipment for use in potentially explosive atmospheres – Part 7: Protection by pressurisation 'p'*

EN 13463-8, *Non-electrical equipment for potentially explosive atmospheres – Part 8: Protection by liquid immersion 'k'*

EN 13617-1, *Petrol filling stations – Part 1: Safety requirements for construction and performance of metering pumps, dispensers and remote pumping units*

EN ISO 2738, *Sintered metal materials, excluding hardmetals - Permeable sintered metal materials - Determination of density, oil content and open porosity (ISO 2738:1999)*

EN 14460:2006, *Explosion resistant equipment*

EN ISO 16852, *Flame arresters – Performance requirements, test methods and limits for use (ISO 16852:2008, including Cor 1:2008 and Cor 2:2009)*

EN ISO 17000, *Conformity assessment – Vocabulary and general principles (ISO/IEC 17000:2004)*

EN ISO/IEC 17021, *Conformity assessment – Requirements for bodies providing audit and certification of management systems (ISO/IEC 17021:2011)*

EN ISO/IEC 17050-2, *Conformity assessment – Supplier's declaration of conformity – Part 2: Supporting documentation (ISO/IEC 17050-2:2004)*

²⁾ This draft standard is now abandoned.

EN 14797, *Explosion venting devices*

EN 14986, *Design of fans working in potentially explosive atmospheres*

EN 15089, *Explosion isolation systems*

EN 24003, *Permeable sintered metal materials – Determination of bubble test pore size (ISO 4003:1977)*

EN 50050, *Electrical apparatus for potentially explosive atmospheres – Electrostatic hand-held spraying equipment*

EN 60079 (all parts), *Explosive atmospheres*

HD 429, *Methods of test for volume resistivity and surface resistivity of solid electrical insulating materials (IEC 60093)*

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

EXPLOSIVE ATMOSPHERES –**Part 34: Application of quality systems
for equipment manufacture**

FOREWORD

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International Standard ISO/IEC 80079-34 has been prepared by IEC subcommittee 31M: Non-electrical equipment and protective systems for explosive atmospheres, of IEC 31: Equipment for explosive atmospheres.

This publication is published as a double logo standard.

This standard should be read in conjunction with ISO 9001:2008.

The text of this particular standard is based on the following documents:

FDIS	Report on voting
31M/45/FDIS	31M/48/RVD

Full information on the voting for the approval of this particular standard can be found in the report on voting indicated in the above table. In ISO, the standard has been approved because there were no negative votes out of the eleven votes cast.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

A list of all parts in the IEC 60079 series, under the general title *Explosive atmospheres*, as well as the ISO/IEC 80079 series, can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC web site under "<http://webstore.iec.ch>" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

INTRODUCTION

This International Standard specifies requirements for a quality system that can be used by an organization for the production of equipment and protective systems for explosive atmosphere.

It can also be used by third parties, including certification bodies, to assess the organization's ability to meet conformity assessments system requirements and/or regulatory requirements.

The application of this standard is intended to cover both electrical and non-electrical equipment and protective systems. The detailed content (e.g. annexes) is currently more focused on the established equipment standards for electrical equipment. However, IEC sub-committee 31M has recently been formed with the responsibility for the development of standards for non-electrical equipment. It is anticipated that, where appropriate, these standards, or requirements related to them, will be referenced within this standard in the future.

Manufacturer's quality requirements are an integral part of most certification schemes and as such this Standard has been prepared with the IECEx equipment certification scheme requirements in mind, is intended to support the ATEX scheme requirements for a manufacturer's quality system and can be applied in other national or regional certifications schemes that relate to the manufacture of explosion-protected equipment.

EXPLOSIVE ATMOSPHERES –

Part 34: Application of quality systems for equipment manufacture

1 Scope

This part of ISO/IEC 80079 specifies particular requirements and information for establishing and maintaining a quality system to manufacture Ex equipment including protective systems in accordance with the Ex certificate.

It does not preclude the use of other quality systems that are compatible with the objectives of ISO 9001:2008 and which provide equivalent results.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

IEC 60050-426, *International Electrotechnical Vocabulary – Part 426: Equipment for explosive atmospheres*

IEC 60079-0, *Explosive atmospheres – Part 0: Equipment – General requirements*

ISO/IEC 17050-1, *Conformity assessment – Supplier's declaration of conformity – Part 1: General requirements*

ISO 9000:2005, *Quality management systems – Fundamentals and vocabulary*

ISO 9001:2008, *Quality management systems – Requirements*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60050-426, IEC 60079-0 and ISO 9000:2005, as well as the following definitions, apply.

3.1

Ex Component

part of Ex equipment or a module (other than an Ex cable gland), marked with the symbol “U”, which is not intended to be used alone and requires additional consideration when incorporated into Ex equipment or systems for use in explosive atmospheres

NOTE This definition is identical to that of IEC 60079-0, except that the term “electrical” has been replaced by “Ex” to allow a broader application of the definition.

3.2

Ex Equipment

machines, apparatus, fixed or mobile devices, control components and instrumentation thereof and detection or prevention systems which, separately or jointly, are intended for the generation, transfer, storage, measurement, control and conversion of energy for the processing of material and which are capable of causing an explosion through their own potential sources of ignition

NOTE This definition includes "equipment" as defined by IEC 60079-0.

3.3

Ex certificate

document that assures the conformity of a product with specified requirements for explosive atmospheres

NOTE 1 The certificate may be either the supplier's declaration of conformity or the purchaser's recognition of conformity or certification (as a result of action by a third party) as defined in the ISO/IEC 17000 series.

NOTE 2 This is equivalent to the term "certificate" as defined by IEC 60079-0.

3.4

manufacturer

organization, situated at a stated location or locations, that carries out or controls such stages in the manufacture, assessment, handling and storage of a product that enables it to accept responsibility for continued compliance of the product with the relevant requirements and undertakes all obligations in that connection

NOTE The term "manufacturer" is used instead of "organization" as used in ISO 9001:2008. For the purposes of this standard they are interchangeable.

3.5

contract

requirements forming an agreement between a manufacturer and a customer and transmitted by any appropriate means

3.6

customer complaint

reported written or verbal allegation made by a customer which concerns the identity, quality, durability, safety, security, conformity or performance of any equipment or protective system or component as defined in the Ex certificate

3.7

product

Ex equipment, protective systems, safety devices, Ex Components and their combinations, as well as software and service as defined in 3.4.2 of ISO 9000:2005

3.8

protective systems

design units which are intended to halt incipient explosions immediately and/or to limit the effective range of explosion flames and explosion pressures

NOTE Protective systems may be integrated into equipment or separately placed on the market for use as autonomous systems.

3.9

safety devices

devices intended for use inside or outside explosive atmospheres but required for or contributing to the safe functioning of equipment and protective systems with respect to the risks of explosion

3.10

schedule drawing

drawing or document listed in the Ex certificate and/or test report

3.11

related drawing

drawing or document not listed in the Ex certificate but linked to the schedule drawing, and used for example, for detailed manufacture of component parts

3.12**technical documentation**

documentation that enables the conformity of the product with the requirements of the standard(s) to be assessed

NOTE 1 This may include schedule drawings when a certification body is involved.

NOTE 2 It covers the design, manufacture and operation of the product and contain:

- a general description;
- design and manufacturing drawings and layouts of components, sub-assemblies, circuits, etc.;
- descriptions and explanations necessary for the understanding of drawings and layouts and the operation of the product;
- a list of the standards referred to in the Ex certificate, applied in full or in part, and descriptions of the solutions adopted to meet the requirements of the Standards;
- results of design calculations made, examinations carried out, etc.;
- test reports.

3.13**manufacturer's documentation**

documents required by a manufacturer but not subject to assessment by body responsible for verification when making an application for a test report or an Ex certificate

EXAMPLE Manufacturing instructions, related drawings, data sheets and sales literature.

3.14**Type of Protection**

specific measures applied to Ex equipment to avoid ignition of a surrounding explosive atmosphere

NOTE This definition is identical to that of IEC 60079-0, except that the term "electrical" has been replaced by "Ex" to allow a broader application of the definition.

3.15**body responsible for verification**

body which conducts documentation review and periodical audit as appropriate

NOTE The body may be either a manufacturer, purchaser, third party or a certification body.

4 Quality management system**4.1 General requirements**

Subclause 4.1 of ISO 9001:2008 applies, with the following addition:

The quality system shall ensure that the product conforms to the type described in the Ex certificate and the technical documentation.

4.2 Documentation requirements**4.2.1 General**

Subclause 4.2.1 of ISO 9001:2008 applies.

4.2.2 Quality manual

Subclause 4.2.2 of ISO 9001:2008 applies.

4.2.3 Control of documents

Subclause 4.2.3 of ISO 9001:2008 applies, with the following addition:

- a) technical documentation and manufacturer's documentation shall be controlled,
- b) documented procedures shall ensure that information contained within manufacturer's documentations is compatible with the technical documentation. The manufacturer shall not initially approve or subsequently amend related drawings unless they are in compliance with the schedule drawings,
- c) the quality system shall ensure that no factor (type, characteristic, position etc.) defined within the Ex certificate and technical documentation (e.g. schedule drawings) is modified,
- d) there shall be a documented system that refers all related drawings to the relevant schedule drawings,
- e) where there are common schedule drawings associated with more than one Ex certificate, there shall be a documented system to ensure simultaneous supplementary action in the event of an amendment to such drawings,

NOTE 1 Some manufacturers use common components with common drawing numbers on more than one product. Some of these products may have different persons responsible for them. Therefore, if one product with a common component and drawing number is revised to meet a need, and if the necessary supplementary certificate is obtained, there needs to be a system for ensuring that any other certificates that call up such components are also subject to supplementary certification. This is in order to avoid such products not being in compliance with their technical documentation. The system should identify the component drawing version, and this version shouldn't be modified by anybody other than the person(s) responsible for the equipment.

- f) where a manufacturer also has drawings for equipment not intended for use in explosive atmospheres, the manufacturer shall have a system that enables both the related drawings and schedule drawings to be clearly identified,

NOTE 2 The following examples indicate some methods of achieving this:

- the use of visual markers;
 - the use of a unique series of drawing numbers, e.g. all drawings concerning a certified equipment have an Ex prefix to the drawing number.
- g) the manufacturer shall document who is responsible for the quality system of each Ex certificate.

NOTE 3 In some certification schemes, the body responsible for the quality system associated with each Ex certificate may be different from the body that issued the Ex certificate and therefore needs to be clearly identified.

- h) where technical documentation or manufacturer's documentation are passed to a third party, they shall be provided in a way that is not misleading,
- i) the manufacturer shall have a documented process to annually check the validity of all Ex related certificates, standards, regulations and other external specifications.

4.2.4 Control of records

Subclause 4.2.4 of ISO 9001:2008 applies, with the following addition:

The manufacturer shall retain adequate quality records to demonstrate conformity of the product and satisfy national regulation and legislation.

NOTE In the absence of specific national regulations and legislation, it is suggested that a minimum of 10 years period be applied.

As a minimum, the list of documents requiring control and retention, as far as applicable, shall be:

- those arising from regulatory requirements;
- customer order;
- contract review;
- training records;
- inspection and test data (per batch);
- calibration data;
- sub-contractor evaluation;

- delivery data (customer, delivery date and quantity, including serial numbers where available).

5 Management responsibility

5.1 Management commitment

Subclause 5.1 of ISO 9001:2008 applies.

5.2 Customer focus

Subclause 5.2 of ISO 9001:2008 applies.

5.3 Quality policy

Subclause 5.3 of ISO 9001:2008 applies.

5.4 Planning

5.4.1 Quality objectives

Subclause 5.4.1 of ISO 9001:2008 applies.

5.4.2 Quality management system planning

Subclause 5.4.2 of ISO 9001:2008 applies, with the following addition:

All the elements, requirements and provisions adopted by the manufacturer in order to ensure compliance of the product with its Ex certificate and technical documentation shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of quality programs, plans, manuals and records.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

Subclause 5.5.1 of ISO 9001:2008 applies, with the following addition:

Responsibilities and authority for the following shall be defined:

- a) the effective coordination of activities with respect to equipment intended for use in explosive atmospheres;
- b) the liaison with the issuer of the Ex certificate (when not issued by the manufacturer) with respect to any proposed change to the design defined in the Ex certificate and the technical documentation;
- c) the liaison with the body responsible for the verification of the quality system with respect to intended updating of the quality system;

NOTE 1 It is not practicable for the manufacturer to inform the body responsible for the verification of the quality system each time the quality system is updated. It is only practicable to inform them of "substantial" updating of the quality system relevant to the type of protection. Similarly, it is not practicable to specify in general terms what types of updating are or are not "substantial". It is therefore recommended that the manufacturer should inform the body responsible for the verification of the quality system on any update of the quality system having consequences on product compliance.

- d) the authorization of initial approval and changes to related drawings, where appropriate;
- e) the authorization of concessions (see 8.3 j));
- f) the customers' information of any applicable specific conditions of use and any schedules of limitations;

NOTE 2 Certificate numbers with a suffix X contain specific conditions of use. Component certificates numbers, (with a suffix U) may contain schedules of limitations.

NOTE 3 For each Ex certificate, it is recommended that an authorized person(s) is (are) appointed who should have responsibility and authority for the above activities so providing an unambiguous focal point within the manufacturer.

- g) the reviewing of Ex certificate and technical documentation and identifying any changes that effect product compliance with the certificate.

5.5.2 Management representative

Subclause 5.5.2 of ISO 9001:2008 applies.

5.5.3 Internal communication

Subclause 5.5.3 of ISO 9001:2008 applies.

5.6 Management review

5.6.1 General

Subclause 5.6.1 of ISO 9001:2008 applies, with the following addition:

- a) the maximum intervals between reviews should normally be 12 months and shall not exceed 14 months;
- b) top management shall chair the review;
- c) the person(s) responsible for the activities as detailed in 5.5.1 shall participate in the review.

5.6.2 Review input

Subclause 5.6.2 of ISO 9001:2008 applies with the following addition:

The review shall include the overall effectiveness of the quality management system with respect to equipment intended for use in explosive atmospheres.

NOTE Results of audits should include both internal audits and those conducted by other parties (e.g. a body responsible for the verification of the quality system, if one is involved).

5.6.3 Review output

Subclause 5.6.3 of ISO 9001:2008 applies.

6 Resource management

6.1 Provision of resources

Subclause 6.1 of ISO 9001:2008 applies.

6.2 Human resources

6.2.1 General

Subclause 6.2.1 of ISO 9001:2008 applies.

6.2.2 Competence, training and awareness

Subclause 6.2.2 of ISO 9001:2008 applies, with the following addition:

The manufacturer shall ensure that all persons having an impact on Ex compliance receive appropriate training.

EXAMPLE People having impact may include those concerned with manufacturing, inspecting, testing, sales, marketing, supply management, calibration and control services and other services.

6.3 Infrastructure

Subclause 6.3 of ISO 9001:2008 applies.

6.4 Work environment

Subclause 6.4 of ISO 9001:2008 applies.

7 Product realization

7.1 Planning of product realization

Subclause 7.1 of ISO 9001:2008 applies.

NOTE Examples are given in Annexes A and B.

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

Subclause 7.2.1 of ISO 9001:2008 applies.

7.2.2 Review of requirements related to the product

Subclause 7.2.2 of ISO 9001:2008 applies with the following addition:

The review shall ensure that any stated customer requirement is compatible with the Ex certificate e.g. equipment group, temperature class, type of protection, EPL and ambient temperature range.

NOTE In some situations, such as internet sales, a formal review may be impractical. In such the information made available to the customer and the order acknowledgement should include as a minimum the Ex marking.

7.2.3 Customer communication

Subclause 7.2.3 of ISO 9001:2008 applies.

7.3 Design and development

7.3.1 Design and development planning

Subclause 7.3.1 of ISO 9001:2008 is not within the scope of this standard.

7.3.2 Design and development inputs

Subclause 7.3.2 of ISO 9001:2008 is not within the scope of this standard.

7.3.3 Design and development outputs

Subclause 7.3.3 of ISO 9001:2008 is not within the scope of this standard.

7.3.4 Design and development review

Subclause 7.3.4 of ISO 9001:2008 is not within the scope of this standard.

7.3.5 Design and development verification

Subclause 7.3.5 of ISO 9001:2008 is not within the scope of this standard.

7.3.6 Design and development validation

Subclause 7.3.6 of ISO 9001:2008 is not within the scope of this standard.

7.3.7 Control of design and development changes

Subclause 7.3.7 of ISO 9001:2008 applies with the following addition:

The person identified in 5.5.1 a) shall approve any changes that could compromise Ex compliance.

7.4 Purchasing

7.4.1 Purchasing process

Subclause 7.4.1 of ISO 9001:2008 applies, with the following addition:

- a) while manufacture, testing and final inspection may be sub-contracted, the responsibility for ensuring conformance with the Ex certificate shall not be sub-contracted;
- b) suppliers that provide a product, process or service that can affect the product's compliance with the Ex certificate, shall only be selected after an evaluation has demonstrated that they have the capability of ensuring compliance with all specified requirements:
- 1) documented objective evidence that the supplier can provide a product, process or service that is fit for its purpose shall be made by one or more of the following methods:

- the supplier has an acceptable Ex quality system,

NOTE 1 A quality system in accordance with this standard is generally acceptable.

- the supplier has a quality system certificate in accordance to the appropriate standard and with an acceptable scope,

NOTE 2 A certificate issued by an accredited body which can demonstrate that it operates in compliance with ISO/IEC 17021 is generally acceptable; depending on the nature of the product, process, or service, a quality system in accordance with ISO 9001:2008 may not be sufficient.

- a documented site assessment to ensure that all relevant controls are available, documented, understood and effective.

NOTE 3 The evaluation should take the following into account:

- criticality of the product, process or service;
- degree of difficulty, or variability in the manufacturing process;
- location of the supplier and hence the effectiveness of communications;
- whether the supplier, in turn, sub-contracts the product, process or service.

- 2) suppliers providing calibration services (including verification on measuring devices by comparison with calibrated equipment) shall be evaluated on their ability to meet stated requirements, in addition to 7.6;
- 3) where the features affecting the type of protection cannot be verified at a later stage, e.g. encapsulated intrinsically safe circuits, then the product, process or service shall only be accepted by one of the following methods:
 - the manufacturer can demonstrate that the control process implemented by the subcontractor ensures Ex compliance,
 - the body responsible for the verification of the quality system performs periodic audits at the sub-contractors.

- c) suppliers not used for a period exceeding one year shall be re-evaluated in accordance with 7.4.1 b) prior to the placing of a contract or a purchase order;
- d) requirements b) and c) are not mandatory for products, processes or services where the manufacturer verifies conformance in accordance with 7.4.3;
- e) the ongoing ability of the supplier to provide conforming product, process or service shall be reviewed at periods not exceeding one year;

NOTE 4 "Review" is a process by which the manufacturer demonstrates the ongoing suitability of their suppliers, e.g. receiving inspection report analysis.

NOTE 5 The terms "re-evaluation" and "review" have different meaning and should not be confused.

- f) the manufacturer shall facilitate an arrangement whereby the body responsible for the verification of the Ex quality system may also verify aspects of any supplier's operation that affects the type of protection.

7.4.2 Purchasing information

Subclause 7.4.2 of ISO 9001:2008 applies, with the following addition:

- a) the purchasing documents shall clearly describe the specific requirements pertaining to subcontracted product set out in the Ex certificate and the technical documentation (e.g. for process control, testing or inspection);
- b) for items where conformance cannot be verified after manufacture (e.g. encapsulated intrinsically safe circuits), the purchasing information shall set out the specific quality procedures, resources and sequence of activities relevant to the particular item;
- c) the manufacturer shall define the method by which documents, e.g. technical specifications, stated in a particular purchase order remain traceable to the order;
- d) where the manufacturer does not provide such documents with subsequent orders, then the manufacturer shall have procedures for ensuring that suppliers have current copies of documents and that their integrity be maintained.

7.4.3 Verification of purchased product

Subclause 7.4.3 of ISO 9001:2008 applies, with the following addition:

- a) for purchased products that can compromise the type of protection the manufacturer shall determine and implement verification arrangements which demonstrate the product's compliance with the Ex certificate, taking into account the nature of the product and the nature of the supplier;
- b) when deciding what type of verification is required for a particular purchased product, the manufacturer shall consider the nature of the purchased product, the supplier and how critical it is to the type of protection.

NOTE In considering whether the supplier should carry out the verification, the manufacturer should take into account the results of the evaluation carried out under 7.4.1. The decision should reflect the competence of the supplier, including whether they have a quality system that covers the activity, the resources, e.g. equipment, and personnel with sufficient skill and experience to do the job. This latter point is particularly significant when judgement is required, such as when inspecting a flameproof casting. When the manufacturer elects to have the supplier carry out tests or inspections relevant to the type of protection, the product should be supplied with a declaration of conformity according to ISO/IEC 17050-1 that confirms it has been done.

- c) where the supplier has been evaluated, and documented objective evidence has been obtained to demonstrate that the supplier is fully capable of producing and verifying the product or service, no further verification of the product or service is required, provided a declaration of conformity according to ISO/IEC 17050-1 is supplied with each batch or product;
- d) where the Ex certificate specifies routine tests or inspections, these shall be carried out on each product. They may be carried out by either the supplier or the manufacturer. When carried out by the supplier, this shall be specified on the purchasing documents, e.g. by a quality plan, and confirmed by the supplier, e.g. by a declaration of conformity according to ISO/IEC 17050-1 including test results, if required;

- e) where verification of a purchased product cannot be carried out after manufacture, e.g. the internal parts of encapsulated intrinsically safe circuits, then the product shall only be accepted if supplied with a declaration of conformity according to ISO/IEC 17050-1. This shall specifically state compliance to the purchase documents, e.g. a quality plan that lists the factors that together demonstrate conformity of the product;
- f) where sample inspections or tests are permitted they shall be conducted in a manner which demonstrates conformity of the entire batch;
- g) where either the supplier or the manufacturer requires training or specialist skills or knowledge to carry out a verification, then the training material, specialist skill, knowledge or background shall be documented and training records maintained;
- h) where the manufacturer chooses not to carry out inspections and tests on his own premises, then inspections and tests shall be performed on the supplier's premises under the responsibility of the manufacturer;
- i) where a supplier provides product with evidence of conformity applicable to use in a explosive atmosphere (e.g. Ex certificate), then further verification is not required unless the manufacturer considers it necessary;
- j) where verification of a purchased product relates to the material (metals, alloys, non metallic parts, resins and similar), a specific analysis certificate or declaration shall be supplied.

7.5 Production and service provision

7.5.1 Control of production and service provision

Subclause 7.5.1 of ISO 9001:2008 applies, with the following addition:

The manufacturer shall provide procedures, production equipment, working environments and inspection/testing facilities that together provide assurance with respect to the compliance of the product with the type as described in the Ex certificate.

7.5.2 Validation of processes for production and service provision

Subclause 7.5.2 of ISO 9001:2008 applies, with the following addition:

Where a process can affect the integrity of a type of protection, and where the resulting integrity cannot be verified after manufacture (e.g. the environmental conditions required for curing an encapsulant), that specific process shall be measured or monitored and documentary evidence shall be maintained to demonstrate compliance with required parameters (see also Annex A).

7.5.3 Identification and traceability

Subclause 7.5.3 of ISO 9001:2008 applies, with the following addition:

- k) the manufacturer shall establish and maintain procedures for product identification during all stages of production, testing, final inspection and placing on the market;
- l) traceability is required with respect to the final product and its significant parts. Traceability can be achieved using serial number, batch or other acceptable method.

NOTE Significant parts include, for example, a printed circuit board (PCB) and a safety component of an intrinsically safe circuit, but not each electronic component on a PCB. The significant part can be defined in the technical documentation during the processes of the product assessment.

7.5.4 Customer property

Subclause 7.5.4 of ISO 9001:2008 applies, with the following addition:

It is the responsibility of the manufacturer to verify the compatibility of the customer supplied product with the requirements of the Ex certificate.

7.5.5 Preservation of product

Subclause 7.5.5 of ISO 9001:2008 applies, with the following addition:

The manufacturer shall provide customers with instructions prepared in accordance with the relevant standards or statutory and regulatory requirements.

7.6 Control of monitoring and measuring equipment

Subclause 7.6 of ISO 9001:2008 applies, with the following addition:

NOTE Compliance can be achieved by using an accredited calibration laboratory (which can demonstrate that it operates in compliance with an internationally recognized standard and is preferably covered by a multilateral agreement) and obtaining a certificate bearing the accreditation logo. Where such a certificate is obtained, the laboratory need not be subjected to further evaluation.

a) Where a calibration certificate does not bear the accreditation logo of a national accreditation authority, each calibration certificate shall include at least the following information:

- an unambiguous identification of the item calibrated;
- evidence that the measurements are traceable to international or national measurement standards;
- the method of calibration;
- a statement of compliance with any relevant specification;
- the calibration results;
- the uncertainty of measurement, where necessary;
- the environmental conditions, where relevant;
- the date of calibration;
- the signature of the person under whose authority the certificate was issued;
- the name and address of the issuing organization and the date of issue of the certificate;
- a unique identification of the calibration certificate.

b) Where a calibration certificate does not bear the accreditation logo of a national accreditation authority or does not contain the information listed in 7.6 a) of ISO 9001:2008, the manufacturer shall demonstrate a valid relationship to international or national measurement standards by other means (e.g. a documented site assessment).

8 Measurement, analysis and improvement

8.1 General

Subclause 8.1 of ISO 9001:2008 applies.

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

Subclause 8.2.1 of ISO 9001:2008 applies.

8.2.2 Internal audit

Subclause 8.2.2 of ISO 9001:2008 applies, with the following addition:

The audit program shall address the effectiveness of the elements of the quality system as described in this standard to ensure that the products are in conformity with the Ex certificate. The maximum period between audits should normally be 12 months and shall not exceed 14 months.

NOTE 1 One method of demonstrating effectiveness is the use of vertical auditing whereby a product awaiting despatch is used to prove the system. The auditor examines all aspects of the system associated with the production of that product from a certification viewpoint. This should include appropriate documentation (drawings, inspection checklists, test records, material certificates, etc.), product identification, handling, storage, training of staff and any other elements of the system which can affect the compliance of the product to the certification parameters.

NOTE 2 For those manufacturers that employ checklists to assist in their internal audit programs then the inclusion of the requirements of this standard into the appropriate checklists and the retention of internal audit records is another alternative method of addressing this requirement.

NOTE 3 Manufacturers may employ either method or some other equivalent method.

8.2.3 Monitoring and measurement of processes

Subclause 8.2.3 of ISO 9001:2008 applies.

8.2.4 Monitoring and measurement of product

Subclause 8.2.4 of ISO 9001:2008 applies, with the following addition:

Where routine tests are required by the Ex certificate and by the technical documentation, these tests shall be performed as specified. Unless specifically permitted by the Ex certificate and the technical documentation, statistical methods shall not be used.

Where practicable, the label bearing the marking data shall not be affixed until the final inspection and testing has been satisfactorily completed.

8.3 Control of nonconforming product

Subclause 8.3 of ISO 9001:2008 applies, with the following addition:

NOTE 1 One of the purposes of this standard is to prevent nonconforming product being supplied.

- a) the manufacturer shall maintain a system such that in the event of the product not complying with the Ex certificate, and having been supplied, then the manufacturer's customer can be identified;
- b) the manufacturer shall take action, appropriate to the degree of risk, where a nonconforming product has been supplied to a customer;

NOTE 2 It is recommended that the manufacturer liaise with the certification body responsible for the issue of the Ex certificate.

- c) where an unsafe nonconforming product has been supplied to a customer, the manufacturer shall inform the customer, in writing as well as the body responsible for the verification of the quality system, and the issuer of the Ex certificate;
- d) where it is not possible to trace the unsafe, nonconforming product (e.g. product supplied via a distributor, or for high volume products such as cable glands) then a notice shall be placed in appropriate publications providing recommended action to be taken;
- e) for all nonconforming product that has been supplied to a customer, the manufacturer shall maintain, for a minimum period of 10 years, records of:
 - 1) serial numbers or identification of products supplied;
 - 2) the customer who received the product;
 - 3) the action taken to inform customers and the body responsible for the verification of the quality system in the case of unsafe nonconforming product;
 - 4) the action taken to implement corrective and preventative action;
- f) concessions for the product that take it outside the design, as defined in the Ex certificate and technical documentation, are not permitted.

8.4 Analysis of data

Subclause 8.4 of ISO 9001:2008 applies.

8.5 Improvement

8.5.1 Continual improvement

Subclause 8.5.1 of ISO 9001:2008 applies.

8.5.2 Corrective action

Subclause 8.5.2 of ISO 9001:2008 applies.

8.5.3 Preventive action

Subclause 8.5.3 of ISO 9001:2008 applies.

Annex A (informative)

Information relevant to particular types of protection and specific products

A.1 General

This annex provides information on those aspects that the quality system should address with respect to particular types of protection. It does not add to or otherwise change the requirements of this standard.

This annex provides examples of how to meet the requirements of this standard, recognizing that other methods which achieve the same objectives are equally acceptable; in addition, it draws attention to aspects of requirements that may not be readily apparent to those unfamiliar with quality systems for products intended for use in explosive atmospheres.

NOTE The following examples do not cover all types of protection but give some advice and will be supplemented in the next edition of ISO/IEC 80079-34.

A.2 Enclosures – General remark

For enclosures and other components forming part of the enclosure and also for fans, fan hoods and ventilation screens, the manufacturer should verify the material composition (e.g. declaration of conformity in compliance with ISO/IEC 17050-1 from the supplier).

Statistical bases are not appropriate to routine tests required by the Ex certificate, except where the following currently permit such techniques:

- the relevant standard;
- appropriate interpretation and clarification sheets;

All measurements should take into account temperature variations.

A.3 Ex d-flameproof enclosures

A.3.1 Verification

Verification consists of a visual inspection and measurement.

The measurement should be carried out with a suitable measuring equipment. The persons doing this measurement should have the competence and knowledge of using this measuring equipment.

A.3.2 Castings

Castings should be subject to verification that demonstrates conformity, e.g.:

- a) 100 % visual inspection should be done on each part;
- b) wall thickness (including those parts not subject to machining);
- c) flaws, inclusions, blow holes and porosity (by either a visual or test method depending upon the criticality).

Recovery of porous castings by impregnation methods, e.g. silicon, is not permitted. In the event that a casting is recovered by welding it will become subject to the requirements applicable to fabricated enclosures, e.g. routine pressure testing.

A.3.3 Machining

Machining should be subject to verification by either 100 % inspection or statistical techniques as appropriate that demonstrates conformity. e.g. the following should be verified:

- a) flatness of flanged flamepaths;
- b) surface roughness of non-threaded flamepaths;
- c) fit of all threaded flamepaths (e.g. cable entries and threaded access covers);
- d) depth of drilling and tapings to ensure adequate residual wall thickness;
- e) dimensional requirements of all flamepaths.

NOTE When statistical techniques are used, this should be in accordance with ISO 3951-1 or equivalent standard.

A.3.4 Cemented joints and potted assemblies

Documented procedures should address the following:

- a) shelf life and storage of cement, potting compounds;
- b) mixing;
- c) surface preparation (degreasing or equivalent is usually required immediately before the potting-operation to ensure good adhesion);
- d) application e.g. filling instructions, freedom from voids and temperature conditions;
- e) curing: this should include curing period, any relevant environmental factors, provision to ensure product is undisturbed during the curing period.

A.3.5 Routine pressure testing

The purpose of the test is to check that the enclosure does not suffer damage or permanent deformation and that there is no leakage from the enclosure during the test other than through constructional gaps, e.g. flamepaths.

Leakage through cemented joints or potted assemblies would constitute a failure.

The test can be a single test conducted on a complete assembly, or a series of tests on each sub-assembly or component part. For enclosures that contain more than one discrete compartment, each compartment should be tested individually. The method used should ensure that the assembly, sub-assembly or component parts are subjected to representative stress patterns e.g. actual fastening facilities are used. Clamping that affects the mechanical properties of the type of protection would invalidate the test results.

Due to safety considerations and difficulty in detecting leakage, hydraulic rather than pneumatic methods are recommended.

The test facility should be adequate to readily provide the required pressure during the test period. Leakage from flamepaths can be reduced by the use of gaskets or 'O' rings.

The pressure gauge should be calibrated, of suitable resolution and range, located such that it does not invalidate the test (e.g. due to pressure drop down pipelines).

The method of test should enable any leakage to be monitored during the test period.

The verification of the routine pressure test should include verification of the product for damage or deformation, e.g. flange flamepaths are still within stated tolerances and fastenings are not stretched.

A.3.6 Flanged joints

Flanged joints should be verified after final assembly to ensure the specified gap is not exceeded. If not possible, special measure should be taken during the production.

A.3.7 Elements, with non-measurable paths, of breathing and draining devices

For products containing elements like sintered metal, pressed metal wire or metal foam, see Annex B.

A.4 Ex i – intrinsic safety

A.4.1 Components for intrinsically safe products

The following features should be verified with respect to the following components for use in intrinsically safe apparatus and associated apparatus. This normally means verifying the marking on the components or packaging and may be achieved by using statistical techniques where appropriate.

Table A.1 – Component features requiring compatibility

Component	Feature
Resistors	Value, power, type, tolerance, case size
Capacitors	Value, tolerance, type, rated voltage, case size
Piezo-electric devices	Manufacturer, type, capacitance
Inductive components	Type, inductance, DC resistance, number of turns, wire gauge and material, material specification of core and bobbin, where appropriate
Transformers	Type, manufacturer, isolation, voltage
Optical isolator	Type, isolation, voltage
Semi-conductors: – diodes – Zener diodes – transistors – integrated circuits – thyristors	Type number, power value and where appropriate, the manufacturer
Cells and batteries	Manufacturer and type number, or IEC designation
Fuses	Manufacturer, type, value
Insulating materials	Specification, dimensions and where appropriate type number
Connectors (e.g. plugs/sockets and terminals)	Type number and where appropriate, the manufacturer

A.4.2 Printed circuit boards (PCB)

A.4.2.1 Non-populated PCBs

PCBs can be accepted with a declaration of conformity in accordance with ISO/IEC 17050-1. The declaration should state compliance to the purchase documents e.g. a quality plan that lists the factors that together demonstrate conformity of the product. For simple single or double sided PCBs, the copper artwork may be visually verified using photographic negative (transparency), certified drawing or controlled inspection sample. Purchase documents should specify copper thickness with tolerances, PCB thickness with tolerances and CTI values.

A.4.2.2 Populated PCBs

Varnish and coatings should be controlled with respect to the specification of material, effectiveness of cover and, where required, application of two independent coverings, i.e. the first covering is allowed to cure or to dry for a suitable time before application of the second covering.

For PCBs, the manufacturer should maintain a list of safety critical components used in production (e.g. resistors and Zener diodes) determined during Ex equipment assessment. The safety critical components placed on the PCB should be verified on a 100 % basis.

Specified distances and clearances on manual assembled PCBs should be verified on a 100 % basis.

This may be conducted by one of the following methods:

- a) a visual verification;
- b) for surface mount components, by ensuring correct loading of the "pick and place" machines and a visual verification of correct placement;
- c) by automatic test equipment (ATE) provided that the ATE addresses each individual safety critical component and by a visual verification is conducted to verify type number of components in shunt Zener diode/diode assemblies.

NOTE Where the surface mount component "pick and place" machine selects the component reel based on measuring the component value, the measuring function should be calibrated.

Documented procedures should be provided that ensure that workmanship standards are defined with respect to component mounting and soldering.

Documented procedures should ensure that segregation of related parts (e.g. terminals) and wiring/cabling is maintained and that specified colours, cross-sectional area, insulation thickness and labels (where appropriate) are fitted.

A.4.3 Sub-assemblies and assemblies

Documented procedures should ensure that production documentation includes all relevant variations to the product design.

Production documentation should address all safety critical components and, in the case of encapsulated parts, the compound manufacturer, type, mix and depth.

Documented procedures should ensure that segregation of related parts (e.g. terminals) and wiring/cabling is maintained and that specified colours, cross-sectional area, insulation thickness and labels (where appropriate) are fitted.

Sealing arrangements should be verified for compatibility with the product's ingress protection rating.

A.4.4 Tests

Any tests specified Ex certificate, e.g. high voltage tests on complete assemblies or individual components such as transformers, should be controlled by documented procedures and conducted on a 100 % basis, unless otherwise permitted.

A.4.5 Intrinsically safe circuits and assemblies housed in Ex d, Ex p or Ex q enclosures

Where Ex d, Ex p or Ex q enclosures contain intrinsically safe circuits, then precautions should be taken as stated in the Ex certificate to ensure that other items listed in the Ex certificate are selected, mounted and installed in accordance with schedule drawings.

A.5 Ex e – Increased safety and nA – Non sparking

A.5.1 Ingress protection

Documented procedures should ensure that the following is verified:

- a) weld continuity;
- b) fitting of gaskets and seals;
- c) continuity of moulded grooves and tongues;
- d) application of cements.

A.5.2 Internal wiring and contact integrity

Documented procedures should ensure that the following are verified:

- a) wiring is effectively clamped;
- b) wiring is correctly terminated, e.g. excessive insulation is not removed from connecting wires (normally within 1 mm of terminal metal);
- c) wiring as specified in the schedule drawings;
- d) connections tightened as specified in the schedule drawings;
- e) creepage and clearances as specified in the schedule drawings have not been compromised.

A.5.3 Rotating machines

Documented procedures should ensure that the following are verified:

- a) rotor end connections and fixing bars are as specified in the schedule drawings;
- b) production controls are in place for
 - the air gap (rotor to stator),
 - the fan clearance,
 - the bearing seal clearances.

A.5.4 Windings

Documented procedures should ensure that the following are verified:

- a) wire and insulation system are as specified in the schedule drawings;
- b) assurance that impregnations are unlikely to contain voids;
- c) insulation materials are as specified in the schedule drawings;
- d) mechanical securing of conductors are as specified in the schedule drawings;
- e) type and mounting of protective devices (e.g. thermal cut-outs) are as specified in the schedule drawings.

A.5.5 Terminal boxes

Documented procedures should ensure that the following are verified:

- a) terminals as specified in the schedule drawings;

- b) creepage and clearances as specified in the schedule drawings have not been compromised.

A.5.6 Cable glands, terminals and other accessories

The dimensions specified in the technical documentation should be confirmed on a statistical basis.

A.5.7 Routine verifications and tests

All routine verifications and tests should be documented. Typically these include:

- a) dielectric tests except for non wired equipment;
- b) verification of the effectiveness of the bearing insulation for insulated bearings (if provided) of rotating machines.

A.6 Ex p – Pressurized equipment

A.6.1 Ingress protection

Documented procedures should ensure that the following is verified:

- a) weld continuity;
- b) fitting of gaskets and seals;
- c) continuity of moulded grooves and tongues;
- d) application of cements.

A.6.2 Components and manufacturing process

The documented procedure should at least ensure the verification of assembling with typical components:

- a) monitoring devices for pressure, differential pressure, purging time, rate of volume, flow, temperature;
- b) Ex-components and Ex-equipment;
- c) enclosure, enclosure parts, materials of enclosure and enclosure parts and gaskets.

A.6.3 Components, constructional characteristics

The documented procedure should include the verification, the manufacturing processes and quality assurance technology for components and constructional characteristics relevant for safety:

- a) purging openings inside the pressurized enclosure or in the enclosure wall;
- b) internal installations (components, partitions, enclosures);
- c) installations into the enclosure wall (components, entries);
- d) purging pipes, purge controller components (internal, external) shall be verified with respect to their constructional specifications and the constructional characteristics.

A.6.4 Routine verifications and tests

All tests should be documented. Typical tests include:

- a) a functional test of the pressurized equipment;
- b) an overpressure of the enclosure;
- c) a leakage test, to ensure the specified maximum leakage rate is not exceeded.

A.7 Ex m – Encapsulation

A.7.1 Production documentation

Thermal protection (e.g. thermal fuses) should be positioned according to, and be of the type specified in, the schedule drawings.

The guidance given in A.3.4 should apply to the compound.

A.7.2 Routine verifications and tests

All tests should be documented. Typical tests include:

- a) visual examination;
- b) dielectric characteristics verification.

A.8 Ex o – Oil immersion

All tests should be documented. Typical tests include:

- a) reduced pressure test (sealed enclosures only);
- b) overpressure test (sealed and unsealed enclosures).

A.9 Ex q – Powder filling

A.9.1 Material control

The material should be of the defined size and type.

Evidence should exist as to the flammability verification of enclosure materials and these materials should align with those specified in the Ex certificate or schedule drawings.

A.9.2 Filling

Filling should be made without voids. Care is clearly needed to ensure that voids are not created after filling by shaking down. The process for filling should be documented and the documentation should include verification criteria.

A.9.3 Ingress protection

Documented procedures should ensure that the following aspects are verified:

- a) weld continuity;
- b) fitting of gaskets and seals;
- c) continuity of moulded grooves and tongues;
- d) application of cements.

A.9.4 Routine verifications and tests

All tests should be documented. Typical tests include:

- a) pressure test;
- b) dielectric strength test of filling material.

A.10 Ex t – Dust ignition protection by enclosure

A.10.1 Casting

Castings should be subject to verification that demonstrates conformity, e.g.:

- a) wall thickness (including the non-machinable parts);
- b) cracks, inclusions, bubbles and porosity.

A.10.2 Enclosure parts

Enclosure parts should be subject to verification that demonstrates conformity, e.g.:

- a) depths of bore holes and tap holes;
- b) dimensional requirements for those enclosure parts relevant for sealing effectiveness or mechanical stability;
- c) insulating coatings and surface conditioning; material, layer thickness.

A.10.3 Gaskets

Documented procedures should address the following:

- a) the gaskets correspond to the quoted specification;
- b) the effectiveness of the sealing elements, e.g. by checking the correct fit of the sealing elements.

If a gasket's correct fit becomes apparent only after assembly, the imprint can be visually examined, e.g. by use of adequate tools such as chalk.

A.10.4 Protection devices

Wherever protection devices (e.g. thermal safety devices) are specified in the Ex certificate, they should be verified according to type and placement.

A.10.5 Cemented and cast enclosure parts

Documented procedures should address the following:

- a) shelf life and storage of cement, potting compounds;
- b) mixing;
- c) surface preparation (degreasing or equivalent is usually required immediately before the potting-operation to ensure good adhesion);
- d) application, e.g. filling instructions, freedom from voids and temperature conditions;
- e) curing, which should include the curing period, any relevant environmental factors, provision to ensure that the product is undisturbed during the curing period.

A.10.6 Ingress protection

Documented procedures should ensure that the following is verified:

- a) weld continuity;
- b) fitting of gaskets and seals;
- c) continuity of moulded grooves and tongues;
- d) application of cements.

A.10.7 Examinations

All examinations should be documented. Typical examinations include:

- a) visual examination;
- b) further examination requirements can result from the concepts given in standards for protection against dust explosion. However, these can essentially be derived from the requirements for the types of ignition protection listed so far.

A.11 Gas detectors

The manufacturer should be required to confirm the regular operation of the measuring function by performing the following checks on each gas detector manufactured:

- a) input and output functions, e.g. operation of displays, LEDs, alarms and push buttons;
- b) sensitivity;
- c) software version.

In addition, the following checks should be performed on a sample basis:

- d) response time;
- e) calibration curve;
- f) response to other gases, if applicable;
- g) long-term stability;
- h) any other check that is considered necessary to confirm the measuring function is in compliance with the relevant standards (for example, effects of temperature or humidity on sensors).

A.12 Flame arresters

Documented procedures should ensure that the following aspects are verified, if relevant:

- a) gap width measurement on the enclosure, between cage and enclosure, on thread openings into the enclosure and between flame arrester and enclosure;
- b) flow measurement;
- c) leak test of housing;
- d) pressure test of housing;
- e) assurance of material properties;
- f) tests of welded joints;
- g) determination of limits of use;
- h) measurement of the triangle's height or of the porosity of the flame arrester;
- i) marking of the pipe connection facilities to be protected.

Annex B (informative)

Verification criteria for elements with non-measurable paths used as an integral part of a type of protection

B.1 General

Sintered material is used in many products, such as gas detectors and loudspeakers.

When the Ex certificate involves such components, then the design parameters for the component normally covers three factors:

- a) maximum bubble pore size;
- b) minimum density;
- c) component construction:
 - for sintered metal and metal foam: material, diameter and thickness,
 - for pressed metal wire: material, wire diameter and mesh size, element thickness.

Therefore, the purpose of this annex is not to add any technical requirements but to provide manufacturers with guidance as to how they can demonstrate that the actual components comply with the design requirements as detailed in the Ex certificate.

B.2 Verification guidance

Three options are available:

- a) the manufacturer conducts the verification examination and tests;
- b) the manufacturer conducts a pre-contract and follow-up periodic documented assessment of the component supplier and accepts sinters with a "declaration of conformity", that is in accordance with ISO/IEC 17050-1;
- c) the manufacturer accepts sinters with a "declaration of conformity" that is in accordance with ISO/IEC 17050-1 from a component manufacturer, who has an acceptable quality management system with an appropriate scope.

B.3 Tests

The tests for all verification options should be performed in accordance with the requirements of the Ex certificate. Typical test requirements are given in ISO 4003 and ISO 2738.

The test may be conducted on a statistical basis, provided that the sample size is not less than 5 % of the batch size. A single failure in the 5 % sample should result in another 5 % being tested; if a failure is detected in the second sample, all sinters in the batch should be 100 % tested. Where tests to determine the maximum bubble pore size and density are conducted on a sample basis, then the results should be calculated to establish the standard deviation (ϕ) for the sample batch, i.e.

- ϕ_p is the maximum bubble pore size standard deviation;
- ϕ_D is the density standard deviation.

The maximum bubble pore size should not be exceeded and the minimum density should remain equal to or greater than the value as stated in the Ex certificate when 3ϕ is taken into

account. Therefore, the mean value of the sample batch, plus $3 \Phi_p$ (for pore size) and minus $3 \Phi_D$ (for density) should not invalidate the requirements of the Ex certificate.

B.4 Test examples

NOTE The following examples for sintered metal are provided for guidance.

B.4.1 Example 1 (pore size)

Maximum permitted bubble pore size as detailed in

- Ex certificate = 150 μm ,
- mean value = 140 μm ,
- standard deviation (σ_p) = 2 μm .

Therefore maximum value = 140 μm + (2 \times 3) μm = 146 μm (PASS).

If standard deviation (σ_p) = 5 μm , then maximum value = 140 μm + (5 \times 3) μm = 155 μm (FAIL).

B.4.2 Example 2 (density)

Minimum permitted density as detailed in

- Ex certificate = 5 gcm^{-3} ,
- mean value = 5,3 gcm^{-3} ,
- standard deviation (σ_D) = 0,05 gcm^{-3} .

Therefore, minimum value = 5,3 gcm^{-3} - (0,05 \times 3) gcm^{-3} = 5,15 gcm^{-3} (PASS).

If standard deviation (σ_D) = 0,12, then minimum value = 5,3 gcm^{-3} - (0,12 \times 3) gcm^{-3} = 4,94 gcm^{-3} (FAIL).

NOTE In some cases, the sinter is formed directly in a solid housing. To establish the density value, the following formula should be used:

$$\rho = \frac{M_1 \times \rho W}{M_2 - M_3}$$

substitute as follows:

$$\rho = \frac{(m_3 - m_1) \times \rho W}{(m_4 - m_1) - (m_5 - m_2)}$$

where

ρW is the density of water;

m_1 is the housing only, weight in air;

m_2 is the housing only, weight in water;

m_3 is the housing and sinter (assembly), weight in air;

m_4 is the coated assembly, weight in air;

m_5 is the coated assembly, weight in water.

B.5 Purchase information

The manufacturer should ensure that the purchase documents include the following:

- the component material specification;
- the dimensional requirements;
- the maximum bubble pore size and the standard called up in the Ex certificate e.g. ISO 4003;
- the minimum density and the standard called up in Ex certificate e.g. ISO 2738.

B.6 Pre-tested components

Where the manufacturer does not conduct his own tests, then the "declaration of conformity" should be in accordance with ISO/IEC 17050-1, and should also include the following:

- the manufactured batch size;
- the sample size taken to establish the maximum bubble pore size and the minimum density;
- the number of components supplied;
- the calculated maximum bubble pore size and minimum density, e.g. the mean values and standard deviation should be stated.

B.7 Measurement and monitoring

Upon receipt of the components, the manufacturer should

- check the "declaration of conformity" against the requirements of Clause B.3,
- check the compatibility of the purchase order requirements with the "declaration of conformity" (if not testing on site and giving special attention to the stated pore size and density data to ensure that when taking the stated tolerance into account the specification is not exceeded,
- conducting the tests (if testing on site),
- conducting a statistical check on the overall size of the component e.g. diameter and thickness.

Bibliography

IEC 60079 (all parts), *Explosive atmospheres*

ISO/IEC 17000 (all parts) *Conformity assessment – Vocabulary and general principles*

ISO/IEC 17021, *Conformity assessment – Requirements for bodies providing audit and certification of management systems*

ISO/IEC 17050-2, *Conformity assessment – Supplier's declaration of conformity – Part 2: Supporting documentation*

ISO 2738, *Sintered metal materials, excluding hardmetals – Permeable sintered metal materials – Determination of density, oil content and open porosity*

ISO 3951-1, *Sampling procedures for inspection by variables – Part 1: Specification for single sampling plans indexed by acceptance quality limit (AQL) for lot-by-lot inspection for a single quality characteristic and a single AQL*

ISO 4003, *Permeable sintered metal materials – Determination of bubble test pore size*

ISO 16852, *Flame arresters – Performance requirements, test methods and limits for use*

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